K010672

GRAMS American Suture, Inc.™

Summary of Safety & Effectiveness
Absorbable Monofilament Suture Synthetic
MONOGRAMS™

This summary is submitted in accordance with the Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR § 807.92. This summary demonstrates the equivalence of Grams American Sutures to those of the legally marked devices listed.

MAY 1 8 2001

A. **Applicant:**

Grams American Suture, Inc.
2225 Dakota Drive
Grafton, Wisconsin 53024 USA

B. **Contact Person:** A. J. Dimercurio

C. **Date Prepared:** March 1, 2001

D. **Device Name:**

- **Trade Name:** MONOGRAMS™ Synthetic Monofilament Absorbable Suture
- **Common Name:** Synthetic Monofilament Absorbable Suture
- **Classification Name:** Absorbable Poly (glycolide/L-lactide) Surgical Suture [Braided & Monofilament]

E. **Predicate Devices:** Monograms™ Synthetic Absorbable Suture is substantially equivalent to these predicate devices:

- SSC'S PCL Monofilament SAS Violet, Coated Synthetic Absorbable Suture, 510K Number K003015, Surgical Specialties Corp.
- Ethicon Monocryl Synthetic Absorbable Monofilament Suture (Poliglecaprone 25) Suture, 510K Number K930772, Ethicon Inc

F. **Device Description:**

Monograms™, is a synthetic monofilament absorbable surgical suture composed of an L-Lactide and *E*-Caprolactone copolymer. Monograms™, is undyed and dyed violet with D&C violet #2 and coated. Monograms™, meets the requirements established by the United States Pharmacopeia (U.S.P.) for synthetic absorbable surgical sutures, except for diameter.

G. Intended Use:

"Monograms™, is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures".

Technological Comparison to Predicate Devices:

COMPARISON TABLE GRAMS TO PREDICATE DEVICES			
Comparison Items	Grams American Suture Inc.	SSC'S PCL Monofilament	Ethicon Monocryl
Suture Material is a composition of absorbable flexible, monofilament thread of homopolymers of *e*-caprolactone and L-lactide	Same	Same	Similar
Suture material is offered undyed and dyed with the FDA listed colorant, D&C Violet No. 2 (21 CFR 74.3602)	Same	Same	Same
Suture Material is supplied coated with a mixture of *e*-polycaprolactone, L-lactide and calcium stearate to enhance its handling properties.	Same	Same	Similar
Suture Material is designed being a sterile, flexible, monofilament thread offered in a variety of lengths and a range of diameters with or without various needles attached.	Same	Same	Same
Suture material absorption begins as a loss of tensile strength without appreciable loss of mass. Implantation studies in animals indicate that Monograms™ retains approximately 82% of its original tensile strength at two weeks post implantation, with approximately 77% remaining at three weeks. Absorption of Gramsorb™ synthetic absorbable surgical suture is essentially complete at 180 days.	Same	Same	Similar but complete absorption is about half the time.
The Suture Material is "Intended for Use" in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures	Same	Same	Same
Suture Material meets or exceeds the performance requirements for "Absorbable Surgical Suture" as defined in the Official Monograph of the United States Pharmacopeia 23 and the current edition USP 24.	Same	Same	Same

Technological Comparison to Predicate Devices (continued)

COMPARISON TABLE GRAMS TO PREDICATE DEVICES			
Comparison Items	Grams American Suture Inc.	SSC'S PCL Monofilament	Ethicon Monocryl
Suture Materials have established similar performance requirements for Diameter that differs from the United States Pharmacopeia 23 and the current edition USP 24	Same	Same	Same
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Tensile Strength" < 881 >	Same	Same	Same
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Needle Attachment" < 871 >	Same	Same	Same
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Suture Length Requirement" (95% of stated label length)	Same	Same	Same
Suture Material is packaged in a same or equivalent manner with sterile single or double package having labeling conforming to 21 CFR and USP XXIV.	Same	Same	Same

Grams American Suture is composed of the same material, as are the predicated devices and the same design' being a sterile, flexible, monofilament threads meeting all the requirements of the United States Pharmacopeia, except for diameter. The Monograms™ Synthetic Monofilament Absorbable Suture is manufactured in the same manner as the predicate devices, being produced from of homopolymers of *e*-caprolactone and L-lactide and produced in operations considered standard in the fiber industry to form the finished suture fiber. The manufacturer supplies to Grams American Suture the same suture materials as it does to other suture manufacturers including some of those listed above.

The biocompatibility data and the results of performance testing presented demonstrate the substantial equivalence of Monograms™ Synthetic Monofilament Absorbable Suture to that of the predicate devices. It further demonstrates Monograms is safe and effective for its intended purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2001

Mr. Anthony J. Dimercurio
Vice President of Operations
Grams American Suture, Inc.
2225 Dakota Drive
Grafton, Wisconsin 53024

Re: K010672
Trade/Device Name: Synthetic Monofilament Absorbable Suture
Regulation Number: 878.4493
Regulatory Class: II
Product Code: GAM
Dated: March 2, 2001
Received: March 6, 2001

Dear Mr. Dimercurio:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010672

GRAMS American Suture, Inc.™

Intended Use Statement

"510(k) Notification"

21CFR 878.4493 Synthetic Monofilament Absorbable Suture

"Monograms™, is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures".

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorati
and Neurological Devices

510(k) Number K010672